

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA,)
ex rel. ROBERT A. FRY, et al.,)
)
)
Plaintiffs,)
)
v.) NO. 3:03-0842
) Judge Trauger/Bryant
GUIDANT CORPORATION, et al.,)
)
)
Defendants.)

MEMORANDUM AND ORDER

Relator Robert Fry has filed his motion to compel discovery (Docket Entry No. 364), seeking an order compelling defendant Guidant to make further response to certain interrogatories and requests for admission. Guidant has responded in opposition to Relator's motion (Docket Entry No. 368), and Relator has filed a reply (Docket Entry No. 394). Guidant has filed a surreply (Docket Entry No. 411-3).

Relator's motion to compel has been referred to the undersigned Magistrate Judge for disposition (Docket Entry No. 365).

For the reasons stated below, the Court **GRANTS** Relator's motion to compel in part and **DENIES** it in part.

Relator's Motion To Compel

Relator challenges Guidant's objections and the sufficiency of its responses to ten interrogatories (Nos. 1, 2, 3, 5, 7, 10, 11, 12, 13 and 14) and ten requests for admission (Nos.

1 through 10). Relator seeks an order overruling Guidant's objections and compelling further responses.

Defendant Guidant maintains that its objections have merit, that its responses are sufficient, and that Relator's motion should be denied.

Interrogatories Nos. 1-3, 5, 7 and 10-11. These interrogatories seek the identity of all Guidant personnel who performed various listed functions: "with responsibility for sales of Devices" (interrogatory no. 1); "in Customer Service Departments . . . who received purchase order information . . ." (interrogatory no. 2); "each head of the Returned Products Department" (interrogatory no. 3); personnel who were "responsible for deciding whether and/or in what amounts to offer the [warranties and credits at issue in this case]" (interrogatory no. 5); "all Guidant personnel responsible for tracking and/or arranging for the payment or account crediting of amounts for credits, warranties or recalls on Guidant Devices" (interrogatory no. 7); "each Guidant sales agent who has been responsible for as many as ten implants or explants for which [credits] (a) were available and (b) have been given" (interrogatory no. 10) and "all Guidant personnel responsible for determining the estimated expenses related to warranty, upgrade, recall or credit expenses for Guidant Devices for the Defendant's annual financial statements" (interrogatory no. 11).

Apparently, in addition to serving objections and narrative responses, several of which have been supplemented, Guidant produced certain organizational charts of the company departments charged with the listed functions and responsibilities (Docket Entry No. 364). Each of Guidant's responses included the following statement: "After reviewing this information, if relator can be more specific in his request for information about current or former Company employees, Guidant will do its best to respond appropriately." Relator in his motion complains that the provided organizational charts "are merely lists of the departments and the personnel who work in them, without any breakdown as to job descriptions or responsibilities." (Docket Entry No. 364-2, p. 10).

In response, Guidant makes several arguments. First, it states that Rule 33(d) permits it to produce pertinent business records in response to interrogatories, and that the subject organizational charts listing departments and personnel, together with the accompanying narrative interrogatory responses, constitute sufficient responses to these interrogatories. In addition, Guidant points out that the subject interrogatories do not ask for a "breakdown as to job descriptions or responsibilities" of the personnel identified, which Relator apparently seeks by his motion. Finally, Guidant asserts that since Relator served these interrogatories he and the United States have conducted Rule 30(b)(6) depositions of Guidant regarding many of the subject

company functions and departments (sales, returned products and warranty departments) (Docket Entry No. 364-1, pp. 10-11, 13-15).

From a review of the filings of the parties, including Guidant's responses to these seven interrogatories and the supplements thereto, the statement that the organizational charts produced by Guidant (though not reviewed by the Court) amount to more than 2,400 pages of documents (Docket Entry No. 368, p. 7), and the additional fact that Relator and the United States have conducted additional discovery regarding these functions by Rule 30(b)(6) depositions, the undersigned Magistrate Judge finds that Guidant's responses are sufficient and denies Relator's motion to compel further responses to interrogatories nos. 1, 2, 3, 5, 7, 10 and 11.

Interrogatory No. 12. Interrogatory No. 12 seeks a description of "the formula used for generating Guidant's estimated expenses related to product warranties for Devices each operating year." In its response, Guidant asserts that there existed no "formula" for estimating future warranty expenses, but that such estimates were based upon many factors, including warranty experience of the company in prior years. In addition, Guidant states that it has produced certain (unspecified) responsive business records pursuant to Rule 33(d), and that the United States and Relator have taken a Rule 30(b)(6) deposition of the company on this issue (Docket Entry No. 364-1, p. 15). Despite this statement in the parties' joint statement, Guidant's response does not reveal

what business records it produced in response to this interrogatory nor how such responsive records were identified or designated.

In view of Guidant's response that no specific formula existed for estimated future warranty expenses, and that plaintiffs have deposed a Rule 30(b)(6) witness (Mr. Cardwell) on this subject, the Court denies Relator's motion to compel a further response to interrogatory No. 12. Nevertheless, if it has not already done so, Guidant shall specify the business records that it has produced in response to this interrogatory sufficiently for plaintiffs to locate and identify them as readily as Guidant could, as required by Rule 33(d).

Interrogatory No. 13. Interrogatory No. 13 seeks the identity of every person that Guidant believes "possesses knowledge or information regarding the factual allegations and/or legal claims" in the complaint and the answer. Guidant's response to this interrogatory lists no person but instead disparages the allegations against the company in the complaint. Guidant does, however, both in its response to this interrogatory and its motion papers, acknowledge its obligation to supplement this response in compliance with Rule 26(e). (Docket Entry Nos. 364, pp. 9-10; 364-1, p. 15 and 368, p. 10).

Rule 26(e), Federal Rules of Civil Procedure, requires that a party supplement its interrogatory response "in a timely manner" if it learns that its prior response is incomplete, unless

"the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing."

Given Guidant's commitment to comply with this obligation, the Court grants Relator's motion to compel a further response to interrogatory no. 13 in compliance with Rule 26(e).

Interrogatory No. 14. Relator in interrogatory no. 14 seeks "the total purchase price collected" by Guidant for Devices which were "covered" by "available" warranty credits, upgrade credits, credits under the Cardiassure program, and/or recalled devices from 1985 to date.

Guidant has objected to this interrogatory on grounds of vagueness, burden and irrelevance. In its response, Guidant asserts that the meaning of the adjective "covered" is unclear and vague because each of its different credit programs had its own distinctive eligibility requirements. Moreover, even when circumstances made a given device eligible for a credit, the credit did not become payable in many cases unless, for example, the hospital returned the explanted device for inspection in a timely fashion and the device had not been damaged by the patient or the hospital.

It appears that Relator, in response to Guidant's objections, abandoned the original interrogatory no. 14 and substituted in its place four new questions limited in time from 1993 to date (Docket Entry No. 364-2, p. 12).

Relator in his reply brief argues that, regardless of whether "conditions" imposed by Guidant were in fact satisfied, Guidant should be required to respond with the total purchase price collected for devices that were "eligible" for warranty or other credits. (Docket Entry No. 394, pp. 4-7). In response, Guidant states that, because of the way in which Guidant's devices are sold and paid for, "the information Relator seeks does not exist, is not kept by Guidant in the course of its business and, consequently, would be unreasonably burdensome for Guidant to calculate." (Docket Entry No. 417, p. 2). By way of example, Guidant maintains that its implantable cardiac devices are typically invoiced to a hospital together with over one hundred other devices as well as multiple other products such as leads or wires (Docket Entry No. 411-2). Although an invoice contains a price for each item listed, the actual price paid by the hospital is affected by many variables, including the provisions of the contract with the specific hospital, the provisions of various incentive rebate programs, whether the hospital qualified for such rebates during a given period, whether a discount for a bulk order was applied, and whether the hospital applied a credit earned on a device implanted in another patient. In summary, because of the large number of variables that can potentially influence the amount actually paid by the hospital for a specific device or group of devices, Guidant states that it does not track the amount actually collected by individual device, and it therefore, "cannot systematically

identify the amount collected – gross or net – for the devices at issue in this case." (Docket Entry No. 417, p. 3).

For the reason that a party cannot be compelled to produce information that it does not have, or could derive with reasonable effort from information it does have, the Court denies Relator's motion to compel further response to interrogatory no. 14.

Requests for Admission Nos. 1, 2, 3 and 4. In these four requests, Relator asks Guidant to admit that, "during the relevant period," it (1) submitted invoices to more than 50 health care providers for Guidant devices implanted as replacements for Guidant devices that were the subject of advisories; (2) submitted more than 1,000 invoices to health care providers for Guidant devices implanted as replacements for recalled devices; (3) received payment from more than 50 health care providers for Guidant devices implanted as replacements for Guidant devices that were the subjects of recalls; and (4) received payment from providers for more than 1,000 Guidant devices implanted as replacements for Guidant devices that were the subject of advisories.

Guidant has objected to these requests on multiple grounds. First, Guidant argues that these requests seek information that is not relevant because (1) the "relevant period," as defined by Relator's requests, predates September 11, 1993, the earliest date for discovery established in this case and (2) these requests, as written, include both devices submitted to the United

States in claims for reimbursement and those not submitted for reimbursement and, therefore not relevant to a False Claims Act case.

Rule 26(b) of the Federal Rules of Civil Procedure provides that a party may obtain discovery regarding any matter to a claim or defense of a party. In addition, this rule provides that "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence."

The undersigned Magistrate Judge finds that these four requests, as framed by Relator, necessarily include devices that are not part of plaintiff's claim and therefore overstate the numbers as they relate to the claims in this case. As a result, responses would be misleading and almost certainly would be inadmissible at trial. Furthermore, given other discovery in this case, responses to these requests would not be reasonably calculated to lead to the discovery of admissible evidence. Therefore, Guidant's objections based upon relevance are sustained, and Relator's motion to compel is denied.

Requests 5, 6 and 7. In requests 5, 6 and 7, Relator seeks to have Guidant admit that, "during the relevant period," Guidant (1) did not pay any warranty credit to health care providers for over 10,000 Guidant replacement devices implanted within the warranty period of the explanted Guidant device. Requests 6 and 7 are identical to Request 5, except they substitute

the words "more than 50,000" and "more than 100,000," respectively.

Guidant objects to these requests on grounds of relevance as with Requests 1 through 4, discussed above, because (1) the "relevant period," as defined by Relator, predates the period of claims in this case and (2) the request as framed includes both devices for which reimbursement claims were submitted to the government and devices not the subject of reimbursement claims. In addition, Guidant has further responded: "Subject to and without waiving these objections, Guidant responds as follows: Guidant has made a reasonable inquiry and the information Guidant knows or can readily obtain is insufficient to enable Guidant to admit or deny this Request."

In his memorandum in support, Relator argues: "Discovery to date indicates that Guidant has had the ready ability to determine when devices were implanted, when they failed, when they were explanted, and the like." (Docket Entry No. 364-2, p. 22). In its response, Guidant challenges this assertion as lacking any support in the record, and states that "Guidant can only determine if a device fails if the device is returned to Guidant and it is tested. Accordingly, Guidant can not – contrary to Relator's baseless assertion – determine when and if a device failed." (Docket Entry No. 368, p. 17).

It appears to the undersigned Magistrate Judge, at least, that the ability to determine when a device "failed" is beside the point because these three requests are not framed in terms of when

a device "failed." Rather, they speak in terms of devices implanted as replacements "within the warranty period of the explanted Guidant device."

Other than explaining why it often does not know when or if a device failed, Guidant has not explained, unless the explanation has been overlooked by the undersigned Magistrate Judge in the multiple filings of the parties, why the "information Guidant knows or can readily obtain is insufficient to enable Guidant to admit or deny" these three requests. Nevertheless, it is true that these requests, by their terms, necessarily include devices that are not included in plaintiffs' claims for the same reasons as Requests 1 through 4 above. For this reason, responses to these requests would almost certainly be ruled inadmissible at trial. Moreover, responses to these requests do not appear to be reasonably calculated to lead to the discovery of admissible evidence.

For the above reasons, the Court denies Relator's motion with respect to Requests Nos. 5, 6 and 7.

Requests 8, 9 and 10. Request 8 asks Guidant to admit that, "during the relevant period," it received "the full invoice price" from health care providers for more than 10,000 devices implanted within the warranty period of the explanted Guidant device. Requests 9 and 10 are identical to Request 8, except they substitute the words "more than 50,000" and "more than 100,000," respectively.

Guidant has objected to these requests on grounds that "the relevant period," as defined in Relator's requests, exceeds the temporal scope of the claims in this case. Similarly, Guidant objects that these requests, by their terms, include both devices that were the subject of reimbursement claims submitted to the government and devices that were not, and therefore any response would be inherently misleading and irrelevant. Finally, Guidant states that it lacks the information necessary to respond to this request because the company does not track prices actually paid for each individual device. See discussion of interrogatory no. 14 on pp. 6-7 above.

Rule 26(b) states that a party may obtain discovery of any nonprivileged matter that is relevant to a claim or defense of a party, and that relevant information need not be admissible at trial if the discovery sought is reasonably calculated to lead to the discovery of admissible evidence.

From a review of the parties' motion papers, the undersigned Magistrate Judge finds that "the relevant period" as defined by Relator in these requests exceeds the period of allowable claims in this case, and that these requests as framed necessarily include both replacement devices billed to the government and those that were not. Therefore, any responses to these requests would necessarily overstate the number of devices and would, therefore, be misleading. Moreover, a number of unrelated variables, such as volume discounts and other sales

incentive programs, affected whether the "full invoice price" was paid for Guidant devices.

For the foregoing reasons, the Court finds that responses to these requests are not relevant and, given the extent of other discovery conducted in this case, not reasonably calculated to lead to the discovery of admissible evidence. Accordingly, Relator's motion to compel responses to requests for admission nos. 8, 9 and 10 is denied.

Production of the "Minnesota documents." Relator's motion also seeks an order compelling Guidant to produce copies of certain documents designated by Relator for copying during an October 2008 document inspection at a Guidant storage facility in St. Paul, Minnesota. The Court has previously ruled on the issues relating to these documents (Docket Entry No. 403), so Relator's motion to compel regarding these documents is moot.

In summary, for the reasons stated above,

(1) the Court **denies** Relator's motion with respect to interrogatories nos. 1, 2, 3, 5, 7, 10 and 11;

(2) the Court **denies** Relator's motion with respect to interrogatory no. 12 except that, if it has not already done so, Guidant shall specify any business records that it has produced in response to this interrogatory in compliance with Rule 33(d), Federal Rules of Civil Procedure;

(3) the Court **grants** Relator's motion with respect to interrogatory no. 13 and **orders** Guidant to supplement its response in a timely manner in compliance with Rule 26(e);

(4) the Court **denies** Relator's motion with respect to interrogatory no. 14;

(5) the Court **denies** Relator's motion with respect to requests for admission nos. 1 through 10; and

(6) the Court **denies** Relator's motion to the extent it seeks an award of fees, costs or other sanctions.

It is so **ORDERED**.

s/ John S. Bryant
JOHN S. BRYANT
United States Magistrate Judge